



To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In October, 2002, claimant submitted a completed supplemental Green Form to the Trust signed by his attesting physician, John R. Harvey, M.D., F.A.C.C. Based on an echocardiogram dated February 5, 2001, Dr. Harvey attested in Part II of Mr. Miskovsky's Green Form that he suffered from moderate aortic regurgitation and a reduced ejection fraction in

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3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

the range of 40% to 49%.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, level II benefits in the amount of \$415,893.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Carl J. Rubenstein, M.D., stated that claimant had "mild aortic dilation and valve thickening." Dr. Harvey, however, attested in claimant's Green Form that Mr. Miskovsky did not suffer from aortic sclerosis. Under the Settlement Agreement, the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive<sup>6</sup> requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). As the Trust does not contest Mr. Miskovsky's entitlement to Level II benefits, the only issue

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4. Dr. Harvey also attested that the claimant suffered from mild mitral regurgitation, bacterial endocarditis associated with either mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). A reduced ejection fraction of less than 50% is one of the complicating factors needed to qualify for a Level II claim.

6. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." Settlement Agreement § I.22.a.

before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In September, 2003, the Trust forwarded the claim for review by Zia Kidwai, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Kidwai concluded that there was no reasonable medical basis for Dr. Harvey's finding that claimant did not have aortic sclerosis. In support of this conclusion, Dr. Kidwai explained: "Aortic valve thickening and calcification is [sic] present. There is presence of aortic sclerosis."

Based on Dr. Kidwai's findings, the Trust issued a post-audit determination that Mr. Miskovsky was entitled only to Matrix B-1, Level II benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that Dr. Kidwai improperly determined that Mr. Miskovsky had aortic sclerosis. In support, claimant submitted a report prepared by Dr. Rubenstein and Michael A. Scherlag, M.D., who stated, in pertinent part:

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Miskovsky's claim.

Review of the 2-5-01 echocardiogram, revealed no evidence of calcification/aortic sclerosis. Although mild aortic valve thickening is present, there is no reasonable medical basis for the auditing cardiologist's finding of the presence of calcification/aortic sclerosis.

In order to confirm this finding, Dr. Scherlag and I reviewed the more definitive Trans-Esophageal Echocardiogram performed by Dr. Scherlag on 2-27-01. This TEE was performed less than thirty days after the 2-5-01 echocardiogram at issue. Because of the more definitive readings obtained from the TEE and the close proximity between the two tests, this TEE study is definitive in confirming our opinions.

The only abnormality revealed on the 2-27-01 TEE involving the aortic valve was severe aortic insufficiency and mild thickening of the aortic valve leaflets. There was no evidence of calcification, sclerosis or stenosis of the valve. There was minimal "debris" noted on the valve indicative of Lambl's excrescences. However, this finding is trivial, and, as stated in Dr. Scherlag's written addition to the original TEE report, that addition being dated 1-24-04, is not associated with the aortic insufficiency. Finally, there was some evidence of atherosclerosis of the aorta, a finding separate from and unrelated to the aortic valve findings.

A review of both the 2-5-01 TTE and the 2-27-01 TEE clearly confirm the absence of calcification/aortic sclerosis in Mr. Miskovsky. There is no reasonable medical basis for any finding to the contrary.

The trust then issued a final post-audit determination, again determining that Mr. Miskovsky was entitled only to Matrix B-1, Level II benefits. Claimant disputed this final

determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Mr. Miskovsky's claim should be paid. On February 1, 2005, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 4427 (Feb. 1, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 23, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and claimant have had an opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare

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8. A [Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.



a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he did not have aortic sclerosis. See id. Rule 24. Ultimately, if we determine that there is no reasonable basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Miskovsky reasserts the arguments made in contest, namely, that there is a reasonable medical basis for the Green Form representations because three cardiologists each found that claimant did not suffer from aortic sclerosis at the time he was first diagnosed as FDA Positive.

In response, the Trust argues that the auditing cardiologist properly applied the reasonable medical basis standard and that Dr. Kidwai did not merely disagree with the attesting physician. The Trust also asserts that claimant has

misinterpreted the reasonable medical basis standard. Finally, the Trust contends that Dr. Kidwai's finding that Mr. Miskovsky has aortic sclerosis is supported by the report of claimant's own experts, which states that "mild aortic valve thickening is present."

The Technical Advisor, Dr. Vigilante, reviewed claimant's record and concluded that there was no reasonable medical basis for the attesting physician's finding that Mr. Miskovsky did not have aortic sclerosis at the time he was first diagnosed as FDA Positive. Specifically, as to the February 5, 2001 echocardiogram, the echocardiogram on which Mr. Miskovsky's Green Form is based, Dr. Vigilante stated,

This study ... showed obvious thickening and calcification of all three aortic leaflets as well as aortic valve annulus.... Classic aortic sclerosis was noted in all views in which the aortic valve was identified including the parasternal long axis view, parasternal short axis view, apical long axis view, and apical five chamber view.

Dr. Vigilante also reviewed a number of additional echocardiograms in claimant's record, (dated October 24, 1997; February 27, 2001; May 31, 2001; and November 21, 2001) and determined that each echocardiogram demonstrated "classic" aortic sclerosis. Accordingly, based on his review of claimant's echocardiograms, Dr. Vigilante concluded that "[a]n echocardiographer could not reasonably conclude that aortic sclerosis was not present on the echocardiogram of attestation or



the other reviewed echocardiograms even taking into account inter-reader variability."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately challenge the specific findings of the Technical Advisor. The Settlement Agreement provides that the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c).<sup>9</sup> Here, Dr. Vigilante determined that claimant suffered from aortic sclerosis as of the time he was first diagnosed as FDA Positive. Specifically, Dr. Vigilante found the presence of "classic" aortic sclerosis on each of claimant's echocardiograms, including Mr. Miskovsky's February 5, 2001 echocardiogram. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

We also reject claimant's argument that the opinions of Dr. Harvey, Dr. Rubenstein, and Dr. Scherlag provide a reasonable medical basis for his claim. In their joint report, Dr. Rubenstein and Dr. Scherlag state that there was "no evidence of calcification/aortic sclerosis," despite finding the presence

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9. There is no dispute that Mr. Miskovsky was first diagnosed as FDA Positive after reaching age sixty (60).

of "mild aortic valve thickening." Neither claimant's experts nor claimant's attesting physician attempt to explain why the thickening of the aortic valve is inconsistent with aortic sclerosis. Moreover, there is no support in the Settlement Agreement for claimant's suggestion that "mild" aortic sclerosis does not require the payment of reduced Matrix Benefits. Unlike some of the other factors that reduce a claim to Matrix B, any presence of aortic sclerosis, regardless of the amount, places the claim on Matrix B. Compare Settlement Agreement § IV.B.2.d.(2)(c)i)c) with Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilation > 5.0 cm").

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he did not have aortic sclerosis at the time he was first diagnosed as FDA Positive. Therefore, we will affirm the Trust's denial of Mr. Miskovsky's claim for Matrix A Benefits and the related derivative claim submitted by his spouse.